UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,428	08/04/2006	Hiroshi Nagai	SHOB-0005 (037498-006)	9228

46188 7590 10/20/2008

THELEN LLP
P. O. BOX 640640
SAN JOSE, CA 95164-0640

EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
10/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,428	NAGAI ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/15/08 has been entered.

Previous Claims and Rejections/Objections Status

2. Claims 1,2 and 4-7 are pending in the application.

3. The rejection of claims 1,2 and 4-7 under 35 U.S.C. 103(a) as being unpatentable over JP 2000-060427A abstract in view of Iwasaki et al. (US 7,014,876B2) and JP 2001-253879 abstract is maintained but modified.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1,2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000-060427A abstract (Derwent Acc-No: 2000-249590) in view of JP 2001-253879 abstract and in further view of Iwasaki et al. (US 7,014,876B2).

6. JP 2000-060427A (Derwent Acc-No: 2000-249590) discloses a black tea health drink containing catechin for improving the function of the liver (title) but does not disclose that the catechin is an O-methylated catechin.

7. JP 2001-253879 discloses O-methylated catechins from tea where R1-R7 is 1-10C alkyl residue.

8. Iwasaki et al. (US 7,014,876B2) discloses a healthy drink containing catechin extracted from tea, such as Oolong tea (column 1, lines 66+; column 2, lines 37-46). The catechins found in Oolong tea (black tea) are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml (column 3, lines 16-20).

9. It is respectfully pointed out that instant claims 1,2 and 4-7 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

10. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize a drink containing catechin or O-methylated catechins to improve liver function. Iwasaki et al. teaches that the catechins found in Oolong tea (black tea) is used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml (column 3, lines 16-20). Therefore it would be obvious to one ordinarily skilled in the art to try/utilize

catechins or O-methylated catechins found in black tea in a health drink, such as one to improve the function of the liver in the amounts of Iwasaki et al. The disclosures of JP 2000-60427A and Iwasaki et al. are drawn to the same utility, such as a health drink containing black tea and therefore the results for varying the amount of catechin would be predictable and lead to improving the function of the liver. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

11. Applicant's arguments filed 7/15/08 have been fully considered but they are not persuasive.

12. Applicant asserts that JP 2000-060427A abstract and Iwasaki et al. (US 7,014,876B2) do not use O-methylated catechin.

13. The references of JP 2000-060427A abstract and Iwasaki et al. were not used to teach the use of O-methylated catechin but was used to teach of the that the catechins found in tea, such as Oolong tea (black tea) are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml and that catechin containing health drinks are used to

improve the function of the liver. The reference of JP 2001-253879 was used to teach that O-methylated catechins are derived from tea.

14. Applicant asserts that the extract obtained from Ti Kuan Yin generally referred to as an oolong tea, it differs from the oolong tea defined in the present claims.

15. The instant claims are product-by-process limitations and therefore the process of “deriving the O-methylated catechins from tea, such as Ohba-oolong" does not impart any patentability. Also, it would have been obvious to try/utilize different Oolong teas to obtain O-methylated catechins for health drinks used for the method of improving the function of the liver as catechin containing health drinks are used to improve the function of the liver.

16. Applicant asserts that the cited publications do not disclose a beverage containing the O-methylated catechins of the presently claimed invention in an amount of 1 to 30 mg/100 ml.

17. Iwasaki et al. teaches that the catechins found in Oolong tea (black tea) is used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml (column 3, lines 16-20). Therefore it would be obvious to one ordinarily skilled in the art to try/utilize catechins or O-methylated catechins found in tea in a health drink, such as one to improve the function of the liver in the amounts of Iwasaki et al. or to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties.

18. Applicant asserts that the cited publications do not disclose that the beverage and composition containing the O-methylated catechins are effective in treating and preventing hepatic functional disorders and hyperlipidemia.

19. The instant claims do not provide any steps and therefore the method of improving the liver function with the black tea health drink containing catechin of JP 2000-060427A encompasses the method of the instant claims.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 112

20. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

21. Claims 1,2 and-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hyperlipidemia or liver disorders, such as cirrhosis and hepatitis does not reasonably provide enablement for treating or preventing all liver and gallbladder disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to utilize the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to a method of using a functional beverage or composition to treat or prevent gallbladder and liver disorders, which encompasses any liver or gallbladder disorders. Various disorders having various different causes are not treatable by a single composition. Given the great diversity between various disorders (haemochromatosis, Wilson's disease, cancer, Gilbert's syndrome, etc.), the unpredictability of treating a subject (e.g., no specific disorder) has a number of facets, as discussed hereinafter.

Treatment of Disease Type

While the state of the art is relatively high with regard to the treatment of specific diseases/disorder with a specific agent, it is long underdeveloped with regard to the treatment of a subject broadly, that is, general treatment, with no specific liver or gallbladder disease/disorder.

Thus, a considerable amount of *in vitro* empirical testing is required, with no *a priori* expectation of success being present, before a candidate for even treating a specific disease, such as, a specific type of liver disease.

2. The breadth of the claims

The claims are very broad and inclusive of "treating or prevent gallbladder or liver disorders" generally, which includes any treatment. Clearly, the methods are only used to treat hyperlipidemia or cirrhosis or hepatitis.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction for ascertaining, *a priori*, which gallbladder and liver disorders can be treated, except cirrhosis and hepatitis.

4. The quantity of experimentation necessary

The lack of adequate guidance from the specification or prior art with regard to the actual treatment fails to rebut the presumption of unpredictability present in this art. Applicants fail to provide the guidance and information required to ascertain which particular gallbladder and liver disorders the claimed agent will be effective against without resorting to undue experimentation. Applicant's limited disclosure of the treatment of is not sufficient to justify claiming all treatment broadly. Such treatment of such unrelated diseases, having various causes and physiology, would no doubt require undue experimentation.

22. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

23. Claims 1,2 and 4-7 provides for the use of a functional beverage but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

24. Claims 1,2 and 4-7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

25. Claims 1,2 and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear and confusing as to what the isomers are included, for example structural isomers or stereoisomers. It is unclear what isomers would be encompasses by the term "isomers" thus the metes and bounds are not defined as the specification fails to define such "isomers".

26. Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. It is unclear as to why the listed teas are in quotations.

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

28. Claims 1,2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000-159670 (abstract) in view of Iwasaki et al. (US 7,014,876B2).

29. JP 2000-159670 discloses a beverage containing an O-methylated catechin extracted from tea leaves. The O-methylated catechin containing beverage of the disclosure encompasses that of the instant claims and therefore is capable of the same functions and has the same properties, such as improving liver function, etc.

30. Iwasaki et al. (US 7,014,876B2) discloses a healthy drink containing catechin extracted from tea, such as Oolong tea (column 1, lines 66+; column 2, lines 37-46). The catechins found in Oolong tea (black tea) are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml (column 3, lines 16-20).

31. It is respectfully pointed out that instant claims 1,2 and 4-7 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in

the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

32. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the catechins or O-methylated catechins found in tea, such as Oolong tea (black tea) in a healthy drink in an amount from 0.092 to 0.5 g per 100 ml as Iwasaki et al. teaches such amounts (column 3, lines 16-20). It would also have been obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties. The instant claims do not provide any steps and therefore the O-methylated catechins containing beverage of JP 2000-159670 encompasses the beverage of the instant claims and is capable of the same method.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618